REMARKS

This is in response to the Office Action mailed on March 1, 2004, and the references cited therewith. For brevity, Applicant incorporates herein by reference arguments already of record during the previous examination of this patent application.

Claims 1, 17, and 31 are amended. No claims are canceled or added. As a result, claims 1, 3-17, and 19-35 remain pending in this patent application.

Interview Summary

Applicant thanks Examiner Oropeza for the helpful telephonic interview on February 19, 2004 between Examiner Oropeza and Applicant's counsel, Suneel Arora. The interview included discussion of Sheldon et al. (U.S. Patent No. 6,044,297) and Ferek-Petric et al. (U.S. Patent No. 5,913,879), however no agreement was reached with respect to the claims.

§112 Rejection of the Claims

Claims 1-30 were rejected under the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, as allegedly introducing non-enabled new matter in the "across a plurality of blood vessels" and "net fluid shift away from the thorax" language that was added by amendment. Applicant respectfully traverses.

Applicant notes that the present patent application incorporates by reference Hauck U.S. Patent No. 5,284,136 (see Application at page 7, lines 26 – 28) and Hartley et al. U.S. Patent No. 6,075,015 (see id. at page 8, lines 4 – 7). Both of these incorporated U.S. patent documents describe, among other things, a four-electrode transthoracic impedance detection system. For example, FIG. 1 of Hartley et al. illustrates using two right ventricular electrodes along with can and housing electrodes on a pectorally-implanted electronics unit. One of ordinary skill in the art would understand that this and other described electrode configurations provide a transthoracic impedance measurement that inherently involves a plurality of blood vessels in the region between the heart and the pectorally implanted electronics unit, and that such a configuration would inherently yield an indication of net fluid shift away from the thorax, as indicated by a change in the measured transthoracic impedance across this region. Therefore, Applicant believes that the present claims are adequately described and enabled by the patent application,

as originally filed, and that no new matter has been entered by amendment to the present claims. Accordingly, Applicant respectfully requests withdrawal of these bases of rejection of these claims.

§103 Rejection of the Claims

1. Claims 1, 3, 4, 8-17, 19, 20 and 23-35 were rejected under 35 USC § 103(a) as being unpatentable over Sheldon et al. (U.S. Patent No. 6,044,297) in view of Pitts Crick et al. (U.S. Patent No. 6,104,949) and further in view of Hudrlik (U.S. Patent No. 5,282,840). Applicant respectfully traverses.

A. No Evidence of Using Transthoracic Impedance to Indicate Hypotension

The Office Action alleges that "Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension." (See Office Action at page 4.) Without admitting that the remainder of the claimed invention is disclosed by Sheldon et al., Applicant agrees with the Examiner's conclusion that Sheldon et al. does not disclose using transthoracic impedance to indicate hypotension. The Office Action apparently relies on Pitts Crick et al. or Hudrlik to establish indicating hypotension using transthoracic impedance.

However, as the Applicant has previously pointed out in an earlier response, Pitts Crick et al. actually pertains to using transthoracic impedance to detect pulmonary edema (fluid accumulation in the thorax), which therefore actually directly teaches away from the claimed hypotensive fluid shift *away* from the thorax. (*See* June 3, 2003 Amendment and Response at page 15.) Therefore, the Office Action has improperly combined Pitts Crick et al. with Sheldon et al., and even when these two conflicting references are combined, they do not yield the claimed methods and apparatuses detecting a hypotensive fluid shift *away* from the thorax.

Likewise, Applicant cannot find any disclosure, teaching, or suggestion in Hudrlik of using a thoracic impedance below about 0.5 Hz associated with a net fluid shift away from the thorax, as presently recited or incorporated in these claims. In fact, Hudrlik actually teaches away from this by measuring thoracic impedance at two frequencies, F1 and F2, that exceed 10 Hz. (*See* Hudrlik at FIG. 3.) Moreover, Applicant respectfully disagrees with the Office Action's assertion that Hudrlik "teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic net shifts in the impedance (col. 2

@ 32 – 35)." (*See* Office Action at page 6.) Hudrlik relates merely to *cardiac* ischemia—absolutely nothing in Hudrlik discloses, teaches, or even suggests detecting a thoracic hypotension associated with a net fluid shift away from the thorax, instead of ischemia within the heart. (*See* Hudrlik at column 3, lines 9-11.) In sum, the Office Action has improperly combined Hudrlik with Sheldon and, moreover, even when these two references are combined, they do not yield the claimed methods and apparatuses using a thoracic impedance below about 0.5 Hz associated with a net fluid shift away from the thorax.

B. No Evidence of Adjusting a Rate Response Factor

The Office Action alleges that:

> Modified Sheldon et al. disclose the claimed invention except for:
> - the responsive hypotension indicator being responsive to thoracic impedance, indicating a fluid shift away from the thorax (claims 1 and 17),
> - a respiration sensor used as a first sensor to define metabolic rate and to provide a base rate for pacing (claims 1 and 17), and
> - a rate responsive factor, being adjusted in response to the hypotension condition indicator (the thoracic impedance signal), the rate responsive factor impacting the pacing rate (claims 1 and 17).

(Office Action ¶ 6.) Without admitting that the remainder of the claimed invention is disclosed by Sheldon et al., Applicant agrees with the Examiner's conclusion that Sheldon et al. does not disclose (among other things) using a rate response factor being adjusted in response to the hypotension condition indicator obtained using a thoracic impedance signal. Instead, the Office Action apparently relies on Hudrlik in attempting to establish this:

> The pacing rate is established based on the first sensor (respiration sensor) and adjusted using a rate responsive factor (having an instantaneous and long-term component) that is based on the hypotension indicator (impedance sensor) (col. 3 @ 9-27; col. 3 @ 59 – col. 4@ 1; col. 6 @ 3-22; col. 10 @ 51 – col. 11 @ 18; col. 11 @ 55 – col. 12 @ 27; col. 12 @ 59-67).

(Office Action at page 6.) Applicant cannot find in these cited portions of Hudrlik any disclosure, teaching, or suggestion of adjusting, in response to the hypotension condition detected using thoracic impedance, a rate response factor mapping: (a) a range in a pacing rate at which stimulations are delivered to the subject's heart; to (b) an activity or respiration sensor signal that is correlative to a range of the subject's metabolic need for cardiac output.

First, as discussed above, Hudrlik merely involves cardiac ischemia, and does not describe any hypotension associated with a fluid shift away from the thorax. Therefore, there can be no teaching or suggestion in Hudrlik of adjusting a rate response factor in response to a detected hypotension associated with a fluid shift away from the thorax.

Second, Applicant notes that the claimed "rate response factor" is not merely any "rate responsive factor," as implied by the Office Action, but instead represents a specific linear or non-linear mapping between a range of an activity or respiration sensor signal that is correlative to a range of the subject's metabolic need for cardiac output (the input variable) and a range in a pacing rate at which stimulations are delivered to the subject's heart (the output variable). Because the Office Action mentions a "rate-responsive factor (having an instantaneous and a long-term component)," Applicant assumes that the Office Action is apparently is relying on the following cited portion of Hudrlik:

> For purposes of monitoring tissue impedance to ascertain changes in tissue condition, the measured impedance amplitudes can be averaged over extended periods of time, for example in the range of days to weeks, so that short term modulation of impedance characteristics of the tissue being monitored due to physical movement, respiration, peristaltic motion, etc. can be disregarded. Alternatively, short term modulation of the relationship between the impedances measured at the two frequencies due to the normal functioning of the tissue (e.g., modulation due to respiration or heartbeats) may be measured and recorded. Changes in the modulation amplitude and rate associated with such tissue-related activities may be measured and similarly be used to detect short or long term changes in tissue condition or overall metabolic functioning.
>
> For example, short term changes in the measured modulation of the relationship of the impedances at the two frequencies due to heartbeats or respiration may be used to control the pacing rate of a cardiac pacemaker.

(Hudrlik at column 6, lines 3 – 22) From this cited passage, it is clear that although Hudrlik apparently does mention using an impedance to control the pacing rate of a cardiac pacemaker, Hudrlik does not mention using a transthoracic impedance associated with a fluid shift away from the thorax to adjust a mapping between an input variable (e.g., patient respiration or patient exercise) and an output variable (e.g., pacing rate). Therefore, the combination of Hudrlik and Sheldon et al. fails to yield the claimed method.

Third, Applicant respectfully submits that Sheldon et al. also fails to disclose the specifically claimed rate response factor mapping. Regarding Sheldon et al., the Office Action states:

> As to the stepping of rate responsive factor (claims 14 – 16 and 27 – 30), pacing therapy is taught as being stepped (col. 7 @ 31 – 34; col. 11 @ 63 – col. 12 @ 9.)

(Office Action at page 4.) These portions of the Sheldon et al. reference that were cited in the Office Action are reproduced below:

> An IMD can provide rapid atrial and/or dual chamber pacing based on knowledge of when the patient is in an or relatively upright posture.

(Sheldon et al. at column 7, lines 31 – 34)

> The durations of the ARP [atrial refractory period], PVARP [post-ventricular atrial refractory period] and VRP [ventricular refractory period] may also be selected as a programmable parameter stored in the microcomputer 34. Digital controller/timer circuit 40 also controls the pulse widths of the APE and VPE pacing pulses and the sensitivity settings of the sense amplifiers 38 by means of sensitivity control 42. Digital controller timer/logic circuit 40 also times out an upper rate limit interval (URL) set by a value programmed into memory in microcomputer circuit 34. This timer is initiated by the occurrence of a VPE or VSE, and limits the upper rate at which ventricular stimuli are delivered to the heart. The lower pacing rate is established by a programmed-in V-A or A-A interval value stored in memory in microcomputer circuit 34.

(Sheldon et al. at column 11, line 63 – column 12, line 9.) Applicant cannot find any disclosure, teaching, or suggestion in these quotations of adjusting a rate response factor, which is specifically defined in the present claims as a mapping between an input variable (e.g., patient respiration or patient exercise) and an output variable (e.g., pacing rate). For example, Applicant respectfully submits that one of ordinary skill in the art would not consider a mere change in posture to constitute an exercise activity level, as presently recited or incorporated in the claims. Moreover, even if one could somehow interpret posture as an exercise activity level, Sheldon et al. merely changes a "rate" in response to a change in posture; it does not change a rate response factor mapping, as specifically defined in the present claims, in response to a change in posture. Thus, the Office Action's claim interpretation appears to equate the term "rate" to the term "rate response factor." However, this claim interpretation ignores the words "response factor," in violation of one of the canons of claim construction, that is, the "rule against surplusage," which

states that a claim must be interpreted in a manner that does not render words superfluous. *See Wright Med. Tech., Inc. v. Osteonics Corp.* , 122 F.3d 1440, 1444 (Fed. Cir. 1997) (applying claim interpretation to avoid superfluity in a claim); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 987 (Fed. Cir. 1995) (analogizing patent claims to statutes); Donald S. Chisum, 5A Chisum on Patents § 18.03[2][a] (same); *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 837 (1988) (noting the rule against surplusage on statutory interpretation). The Office Action's claim interpretation also ignores the claim language specifically defining the adjusting the rate response factor as the adjusting of a mapping between a particular input variable (e.g., patient respiration or patient exercise level) and an output variable (e.g., pacing rate).

In view of the above, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 5-7, 21 and 22 were rejected under 35 U.S.C. § 103(a) for obviousness over Sheldon et al. (U.S. Patent No. 6,044,297) in view of Pitts Crick et al. (U.S. Patent No. 6,104,949) and further in view of Hudrlik (U.S. Patent No. 5,282,840) and further in view of Combs et al. (U.S. Patent No. 5,957,861). Applicant respectfully traverses.

The Office Action states that "modified Sheldon et al. disclose the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 Hz to 0.5 Hz, or approximately 0.1 Hz." (Office Action at 7.) Without admitting that the remainder of the claimed invention is disclosed by Sheldon et al., Applicant agrees with the Examiner's conclusion that Sheldon et al. does not disclose the cutoff frequency for the fluid impedance signal being 0.01 Hz to 0.5 Hz, or approximately 0.1 Hz. The Office Action apparently relies on Combs et al. for this missing element. However, not only is there no motivation to combine Sheldon et al. with Combs et al. drawn from either of these references, it is also wholly inappropriate to combine these references in this manner. As discussed above and in a previous response, Combs et al. and Pitts Crick et al. both relate to pulmonary edema (i.e., fluid accumulation in the thorax) instead of thoracic hypotension (i.e., a fluid shift *away* from the thorax). Therefore, Combs et al. actually expressly teaches away from the present claims and from being combined with Sheldon et al. Furthermore, Hudrlik actually teaches away from using a thoracic impedance below about 0.5 Hz, as discussed above. Therefore, Applicant

respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 1, 3, 8-10, 13, 17, 19, 20, 23-36 and 31-35 were rejected under 35 U.S.C. § 103(a) for obviousness over Ferek-Petric (U.S. Patent No. 5,913,879) in view of Standberg (EP 0620420A1) and further in view of Hudrlik (U.S. Patent No. 5,282,840). Applicant respectfully traverses.

The Office Action states:

> Ferek-Petric et al. teach an implantable therapy device that detects venous pooling (correlative to hypotension), read as detecting fluid shift away from the thorax, using a flow detector . . .

(Office Action at page 8.) Ferek-Petric et al. apparently uses an impedance (not specifically a transthoracic impedance) to measure blood flow, not how much fluid is present in the thorax. (*See* Ferek-Petric et al. at column 2, lines 51 – 55.) It does so by using a sensor implanted within the right heart (*see id.* at column 3, lines 16 -18) to measure venous pooling, which is presumably indicated by a reduced venous return flow (*see id.* at column 3, lines 33 – 34). However, Applicant can find nothing in the cited portions of Ferek-Petric et al. that would be capable of distinguishing between venous pooling in the thorax and venous pooling in the lower extremities representing a fluid shift away from the thorax—both of these circumstances would presumably result in reduced venous flow. By contrast, these claims of the present patent application involve using a transthoracic impedance to accurately detect and treat a hypotension resulting from a fluid shift *away* from the thorax, which the Office Action admits is not disclosed in Ferek-Petric. (*See* Office Action at 8.) This is accomplished, as recited or incorporated in the present claims, by using a transthoracic impedance that is associated with a portion of the subject's thorax that "includes a plurality of blood vessels," which excludes Ferek-Petric's flow sensor implanted within the right heart.

The Office Action apparently relies on Hudrlik to establish using transthoracic impedance to detect a fluid shift away from the thorax. (*See* Office Action at 8.) However, as discussed above, Hudrlik relates merely to *cardiac* ischemia instead of thoracic hypotension, and Hudrlik actually teaches away from using a thoracic impedance below about 0.5 Hz, as presently recited or incorporated in these claims. Therefore, Applicant respectfully submits that no *prima*

facie case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

4. Claims 4-7, 21 and 22 were rejected under 35 U.S.C. § 103(a) for obviousness over Ferek-Petric (U.S. Patent No. 5,913,879) in view of Standberg (EP 0620420A1) and further in view of Hudrlik (U.S. Patent No. 5,282,840) and further in view of Combs et al. (U.S. Patent No. 5,957,861). Applicant respectfully traverses for the reasons discussed immediately above with respect to the § 103 rejection using Ferek-Petric, Standberg, and Hudrlik. Although this rejection adds the Combs et al. reference as an additional basis of rejection, as discussed above, it is improper to combine Combs et al. with any reference alleged to establish hypotension detection, such as Ferek-Petric, because Combs et al. actually expressly teaches away from detecting a hypotensive fluid shift *away* from the thorax. Instead, Combs et al. pertains to detecting pulmonary edema, which is a fluid *accumulation* in the thorax. Therefore, it is improper to combine Combs et al. with Ferek-Petric and, even if combined, these and the other references to not yield the claimed methods and apparatuses that use thoracic impedance to detect and treat a hypotensive fluid shift *away* from the thorax. Therefore, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Objection to the Specification

The amendment filed January 23, 2004 was objected to under 35 U.S.C. 132 as introducing new matter into the disclosure. However, for the reasons discussed above, Applicant believes that the "across a plurality of blood vessels" and "net fluid shift away from the thorax" language is fully supported by the present application as originally filed. Therefore, Applicant respectfully requests withdrawal of this basis of objection to the specification.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, MS: Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10 day of June, 2004.

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